

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**

42. (New) A composition comprising a compound according to claim 1, wherein one or more individual amino acids is replaced by an analogous structure.

### REMARKS

Claims 1-33 were pending in the present application. Claims 16-18, 21, 23, 25, and 27-33 were previously withdrawn from consideration as being drawn to a non-elected invention. By virtue of this response, claims 14-15 and 19-20 have been cancelled, claims 1-4, 6-13, 22, 24, and 26 have been amended, and new claims 34-42 have been added. Accordingly, claims 1-13, 22, 24, 26, and 34-42 are currently under examination.

The claim amendments and new claims are supported by the specification as follows:

The amendments to claims 1 are supported in the specification for example on page 6, lines 6-29 and on page 8, lines 8-27. The amendment to claim 2 is supported in the specification for example on page 6, lines 30-32. The amendment to claim 3 is supported in the specification for example on page 6, lines 33-35. The amendment to claim 4 is supported in the specification for example on page 6, lines 35-36. The amendments to claim 6 are supported in the specification for example on page 6, lines 6-29, on page 7, line 33 - page 8, line 3, and on page 8, lines 8-27. The amendments to claim 7 were made to correct clerical errors and are supported in the specification for example in Figure 12. The amendment to claim 8 is supported in the specification for example on page 8, lines 19-21. The amendment to claim 9 is supported in the specification for example on page 8, lines 14-15. The amendment to claim 10 is supported in the specification for example on page 8, lines 23-27. The amendment to claim 11 is supported in the specification for example on page 10, lines 15-20. The amendment to claims 12 and 13 are supported in the specification for example on page 10, lines 7-10 and on page 10, lines 15-20. The amendment to claim 22 is supported in the specification for example on page 9, lines 15-18 and on page 8, lines 8-27. The amendment to claims 24 and 26 are supported in the specification

for example on page 9, lines 26-32 and page 8, lines 8-27. New claim 34 is supported in the specification for example on page 7, line 23 - page 8, line 3. New claims 35-38 are supported in the specification on page 9, lines 9-10 and on page 8, lines 11-27. New claim 39 is supported in the specification for example on page 9, lines 11-14. New claims 40-42 are supported in the specification for example on page 8, lines 11-27. Thus, no new matter has been added by the foregoing amendments.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned “**VERSION WITH MARKINGS TO SHOW CHANGES MADE**”.

With respect to any claim amendments or cancellations, Applicant has not dedicated to the public or abandoned any unclaimed subject matter and moreover has not acquiesced to any rejections and/or objections made by the Patent Office. Applicant expressly reserves the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Applicant has carefully considered the points raised in the Office Action and believes that the Examiner’s concerns have been addressed as described herein, thereby placing this case into condition for allowance.

#### ***Election/Restriction Requirement***

The Examiner acknowledges Applicant’s election of Group I and the species of SEQ ID NO:1. However, the Examiner incorrectly states that the election of Group I was traversed based on the “special technical feature” of disulfide bonding among the four cysteine residues at positions 173, 176, 183, and 186. In response to a restriction requirement dated May 12, 2000 (paper no. 9), Applicant elected Group I (claims 1-11, drawn to a compound, diagnostic, and pharmaceutical compound), with traverse, in a response dated June 12, 2000. Applicant traversed the restriction requirement on the basis that the compounds of Group I and claims to

their uses have unity of invention, i.e. the invention of Group II (drawn to antibodies) is defined, in part, by the claimed antibodies' ability to bind the compounds of Group I. Applicant stated that all of the claims share the compound of claim 1 as a special technical feature in common, so there is unity of invention between all claims. After amendment of the claims, a further restriction requirement was issued on September 21, 2000 (paper no. 14). In a response to this requirement, dated November, 21, 2000, Applicant elected Group I (claims 1-15, 19-20, 22, 24, and 26, drawn to a compound, diagnostic, and pharmaceutical compound, and a method of prevention or treatment) *without traverse*. Therefore, the Examiner's reference to Alkerlind-Stopner et al. (*J. Virol.* 64:5143-5148 (1990)) as allegedly anticipating a special technical feature relating to disulfide bonding between cysteine residues in the claimed invention is inappropriate and does not relate to any statements previously made by Applicant during prosecution. Further, the Examiner's statement that Applicant elected Group I with traverse is also incorrect.

The Examiner also incorrectly states that Applicant elected the species of SEQ ID NO:1 with a traversal based on all of the sequences in claim 5 (SEQ ID NOs: 1-18) being of the same length and having the same amino acid residues at each position. In response to an election of species requirement dated March 7, 2001 (paper no. 18), Applicant elected the species of SEQ ID NO:1. In that response, dated May 2, 2001, Applicant noted that all of the sequences in claim 5 (SEQ ID NOs:1-18) were of the same *length*, in response to the Examiner's statement that the species of peptides all have "different molecular structure in length or in amino acid." Therefore, the Examiner's statement that Applicant traversed the election of species requirement based on the peptides of claim 5 being of the same amino acid sequence is incorrect and does not relate to any statements previously made by Applicant during prosecution. With regard to the Examiner's statement that the difference in amino acid sequences between the peptides claimed in claim 5 renders them structurally different products, with different biological effects, the Examiner has provided no evidence to support such a statement, particularly with respect to the assertion that the peptides of claim 5 produce different biological effects.

***Priority***

The Office Action stated that an application in which the benefit of an earlier application is desired must contain a specific reference to the prior application(s) in the first sentence of the specification, pursuant to 37 C.F.R. §1.78. The specification has been amended to include priority information. Withdrawal of the request to add the priority statement is respectfully requested.

***Rejections under 35 U.S.C. §112, second paragraph***

Claims 1-15, 19-20, 22, 24, and 26 are rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite.

A. Claim 1 is rejected because the metes and bounds of “respiratory syncytial virus” are allegedly not defined. Applicant respectfully traverses this rejection. Applicant notes that the specification extensively discusses the family of respiratory syncytial viruses (RSVs), for example on pages 2-4, and shows that regions in the F and G proteins are highly conserved. The sequence conservation in the G protein is further discussed in the specification, for example on page 10, line 29 - page 11, line 4. The specification discloses that there is a particularly high degree of conservation in the region of the G protein which is the subject of the claimed invention. For example, Figure 2 shows the sequence encompassing amino acid residues 149-197 of the G proteins of a number of human RSVs of both A and B subtypes, as well as those of human variants and of bovine RSVs, clearly demonstrating the strong sequence conservation between RSVs. Thus, in the absence of specific experimental evidence to the contrary, Applicant submits that there is no reason to believe that the claimed invention will not be applicable to *all* members of the RSV family.

B. Claims 1, 5, and 6 are rejected because recitation of the term “having” allegedly renders the claims indefinite. The Examiner states that the term “having” is open language that

allegedly lacks patentable weight for precisely defining the structure of the claimed compound. Applicant respectfully traverses this rejection.

Applicant maintains that the term “having,” as used in the claims, would be readily understood by one of skill in the art to mean characterized by, which is a dictionary definition for this term (Webster’s New Ideal Dictionary, p. 233, 1973). Applicant notes that claims 1 and 6 as amended no longer contain the term “having,” rendering this rejection moot with respect to those claims.

The Examiner states that the phrase “having structural homology” is unclear in claims 1 and 6 with respect to defining homology between sequences, because identity, homology, and sequence similarity can be calculated by a variety of methods. In response, Applicant submits that the concept of structural homology is well understood by those skilled in the art, and it would be a matter of routine to design compounds having three-dimensional structural homology to the claimed sequence on the basis of the disulfide bonding pattern specified in claim 1. This is a completely different concept from that of sequence homology or sequence identity, which are the concepts that are discussed by the Examiner. These concepts relate to the substitution or deletion of individual amino acids within a sequence, rather than three-dimensional conformation.

C. Claim 2 is rejected because the metes and bounds of the phrase “mutants and variants thereof” are allegedly not defined. Applicant respectfully traverses this rejection. The terms “mutant” and “variant” are well understood by those of skill in the art to refer to a viral strain that differs from another strain in terms of sequence variation. Since RSV strains are subject to naturally-occurring variation, it would be unduly restrictive if the claims were limited to specific strains. In view of the high degree of conservation of the G protein across RSV strains (see, for example, Figure 2), any mutant or variant of the RSV types and subtypes listed in claim 2 would be expected to possess the same disulfide bonding pattern as that specified in claim 1. Further, if a new strain, mutant, or variant were identified and isolated, which could be readily performed

using routine methods, it would also be a matter of routine for a person of ordinary skill in the art to isolate its G protein, to determine the sequence of that protein, and to synthesize a compound within the scope of the claims using the teachings set forth in the specification.

D. Claim 8 is rejected as allegedly vague due to recitation of the phrase “peptidomimetic compound.” Applicant respectfully traverses this rejection. “Peptidomimetic” is a term that is well understood in the art, and is defined in the specification, for example on page 8, lines 19-21, as a peptide analogue “in which the peptide bond is replaced by a structure more resistant to metabolic degradation.” One skilled in the art would have no difficulty understanding the scope of this term, particularly in light of the passage from page 8, line 9 to page 9, line 2 of the specification.

E. Claim 14 is rejected because the metes and bounds of “an acceptable carrier” are allegedly not defined. Applicant respectfully traverses this rejection. The term “acceptable carrier” would be readily understood by a person skilled in the art to mean a substance that is compatible with other components of a composition. “Acceptable carrier” is a well-recognized term in claims to compositions. Applicant notes that claim 14 has been canceled, rendering this rejection moot with respect to this claim.

F. Claims 19 and 20 are rejected because the metes and bounds of “respiratory syncytial virus” are allegedly not defined. Applicant respectfully traverses this rejection. As discussed above, this family of viruses and the sequence conservation in the claimed region of the G protein, are extensively described in the specification. However, Applicant notes that claims 19 and 20 have been canceled, rendering this rejection moot with respect to these claims.

G. Claims 22, 24, and 26 are rejected as allegedly incomplete for omitting essential steps. The Examiner states that the method of administration of the claimed compound into the recipient and the method of determining the resulting immunity of the individual to *Pneumovirus* are essential omitted steps. Applicant respectfully traverses this rejection. Applicant submits that there is no need to specify these steps because they are common to the art and are not

required to distinguish the claimed invention from the prior art. These steps are not “essential elements of the invention as defined by applicant(s) in the specification,” as required to sustain a 35 U.S.C. §112, second paragraph rejection (MPEP § 2712.01). Therefore, the rejection is improper.

H. Claim 26 is rejected because there is allegedly insufficient antecedent basis for the limitation “cell” in this claim. Claim 26 has been amended to recite the term “mammal” instead of “cell.” Antecedent basis for the term “mammal” is provided in claim 24, the claim upon which claim 26 depends.

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. §112, second paragraph.

***Rejections under 35 U.S.C. §112, first paragraph***

A. Claims 1-7, 14, and 19 are rejected under 35 U.S.C. §112, first paragraph, as allegedly not enabled for a diagnostic composition comprising a synthetic G protein. As an initial matter, Applicant notes that of the rejected claims, only claims 14 and 19 relate to diagnostic compositions. (Claims 1-7 relate to a compound comprising residues 149-197 of the G protein of RSV.) Therefore, the enablement rejection appears to encompass only claims 14 and 19. Applicant notes that claims 14 and 19 have been canceled, rendering this rejection moot with respect to these claims. However, Applicant maintains that the specification is enabling with respect to diagnostic compositions.

The Examiner alleges that the field of diagnosis of RSV with the claimed peptides is “unpredictable” and that the affinity of the peptide for “any or all RSV element[s]” is “questionable” because the specification presents evidence of the binding of a labeled peptide to only one cell line, HEp2 (paper no. 21, page 5). In response, Applicant maintains that it is not



necessary to show that the peptides of the invention bind to “any or all RSV elements.”

Applicants have demonstrated in the specification that peptide derivatives of the invention are able to bind to the cellular receptor for RSV and inhibit the cytopathic effect of the A2 strain of human RSV on RSV susceptible cells (see, for example, Example 6). This binding activity to the RSV receptor renders the compounds of the invention useful as diagnostic agents, for example in a screen to identify compounds capable of inhibiting binding of the virus to its host cell (see for example page 9, lines 3-25 of the specification). The HEp-2 cells which are used in these experiments are a well-recognized model system for testing biological activity against RSV, as evidenced by this cell line’s designation as “Host of Choice” with respect to RSV strains in the ATCC Catalogue of Animal Viruses and Antisera, Chlamydia and Rickettsiae, 6th Ed., 1990, page 83, a copy of which is attached to this response. It would be a matter of routine to extend the example provided in the specification to assays using other claimed peptide analogues of the invention. A skilled artisan in possession of the information set forth in the specification would be able to develop diagnostic assays, produce further analogues suitable for use in diagnostic compositions, and test the reliability of the assays as a matter of routine, using methods which are well known in the art, without undue experimentation. The Examiner has provided no objective, substantial evidence to suggest otherwise.

The Examiner’s statement that “the extracellular domain of the G protein has a high degree of strain-to-strain diversity” (paper no. 21, page 5) is irrelevant, because the region of the G protein which is the subject of the claimed invention is highly conserved (see, for example, Fig. 2 of the specification).

The Examiner states that “[t]he leve[l] of skill in the RSV diagnosis with peptide is high and significant hurdles remain to be overcome in order for the skilled artisan to practice successful gene therapy.” (paper no. 21, page 6) Applicant notes that if the level of skill in the art with respect to RSV diagnosis is high, as the Examiner has stated, it would be a matter of routine to develop diagnostic assays based on the claimed compositions. Further, Applicant

notes that the claims at issue are not directed to “gene therapy,” but rather are directed to diagnostic compositions.

B. Claims 1-13, 15, 20, 22, 24, and 26 are rejected under 35 U.S.C. §112, first paragraph, as allegedly not enabled for a method for prevention or treatment of human RSV. As an initial matter, Applicant notes that of the rejected claims, only claims 22 and 24 relate to methods for prevention or treatment of human RSV, while claim 26 relates to a method for immunization against *Pneumovirus* infection. (Claims 1-13 relate to a compound comprising residues 149-197 of the G protein of RSV and claim 15 relates to a pharmaceutical composition comprising a compound comprising residues 149-197 of the G protein of RSV.) Therefore, the enablement rejection appears to encompass only claims 22 and 24, and possibly claim 26.

Applicant maintains that the specification is enabling with respect to methods for prevention or treatment of human RSV infections. As discussed above, Example 6 of the specification demonstrates that peptide derivatives of the invention are able to inhibit the cytopathic effect of RSV on HEp2 cells. This antiviral activity renders these compounds useful as therapeutic agents, for example in a method of prevention or treatment of *Pneumovirus* infection comprising administering an effective amount of a compound of the invention to a mammal in need of such treatment, or in a method for immunization of a mammal at risk of RSV infection with an immunizing-effective dose of a compound of the invention (see for example page 9, lines 3-37 of the specification). Application of the invention to preventative or therapeutic methods with respect to RSV would be a matter of routine to one of skill in the art, and the Examiner has provided no objective, substantial evidence to suggest otherwise.

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. §112, first paragraph.

***Rejection under 35 U.S.C. §102(e)***

Claims 1-6, 8, 10, 14-15, 19-20, 22, 24, and 26 are rejected under 35 U.S.C. §102(e) as allegedly anticipated by Langedijk (U.S. Pat. No. 6,077,511). Applicant respectfully traverses this rejection.

As an initial matter, Applicant notes that the §102(e) date of the Langedijk reference is February 25, 1997. This date is after Applicant's priority date of June 5, 1996. Therefore, Langedijk is ineffective as a §102(e) reference. However, even if the §102(e) date of Langedijk were before Applicant's priority date, this reference would not anticipate Applicant's invention for the following reasons:

The Langedijk reference identifies a small region of RSV G protein as being useful for vaccines and diagnostic test kits. This is an independently folding region (column 4, lines 5-9). However, as the Examiner has conceded, the pattern of disulfide bonding was not determined, and since synthetic, oxidized peptides were used, it cannot be assumed that the *native* pattern of disulphide bonding was present in the peptides disclosed in Langedijk. Applicant respectfully traverses the Examiner's statement that the disulfide bonding pattern specified by the claimed invention is an inherent characteristic of the claimed peptides. It is essential to confirm whether a synthetic peptide, as in Langedijk, adopts the native disulfide bonding pattern by an empirical determination of the bonding pattern in both the synthetic peptide and the native protein, and a comparison of the two. It would not have been possible to predict the native pattern of disulfide bonding from the disclosure of Langedijk. The instant invention is based in part on Applicant's elucidation of the specific disulfide binding pattern within the highly-conserved, cysteine-rich region of the ectodomain of the RSV G protein. The functional importance of the disulfide binding pattern is discussed for example on page 40, line 14 to page 41, line 22.

In order for a reference to anticipate a claimed invention, each and every element of the claimed invention must be disclosed in the reference. Since Langedijk does not disclose a

pattern of disulfide bonding wherein Cys 173 is linked to Cys 186 and Cys 176 is linked to Cys 182, as required by the present claims, Langedijk does not anticipate the claimed invention.

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §102(e).

***Rejection under 35 U.S.C. §102(b)***

Claims 1-6, 8, 10, 14-15, 19-20, 22, and 24 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Alkerlind-Stopner et al. (*J. Virol.* 64: 5143-5148 (1990)). Applicant respectfully traverses this rejection.

The reference by Alkerlind-Stopner is discussed at page 3, lines 28 to 33 of the specification. This reference merely shows that the cysteine-containing region of the RSV G protein has possible potential as a sub-type specific determinant. However, the authors concluded that “. . . the activity of the antigenic site in tests with monoclonal antibodies for subgroups A and B appears to depend on intrapeptide disulfide bonds. Reactions with post infection sera of subgroup B also may depend on a disulfide bond. In contrast, postinfection sera of subgroup A appeared to have the capacity to identify a subgroup-specific site in a linear form of the selected 15-amino-acid long peptide. Treatment of peptides with dithiothreitol had no effect on their antigenic activity in tests with human postinfection sera of subgroup A.” (p. 5143)

These findings have relevance for molecular engineering of peptide antigens for use in respiratory syncytial virus subgroup-specific site-directed serology. In other words, the authors were examining the specificity of this immunodominant antigenic site, and its possible ability to provide a subgroup-specific diagnostic test for epidemiological purposes. However, they did not disclose or suggest the *pattern* of disulfide bonding, which is a basis of the present invention. In view of the fact that synthetic peptides rather than native protein were used in the experiments of the cited reference, it cannot be assumed that these peptides contained disulfide bonds in the manner required by the present claims.

In order for a reference to anticipate a claimed invention, each and every element of the claimed invention must be disclosed in the reference. Since Alkerlind-Stopner does not disclose a pattern of disulfide bonding wherein Cys 173 is linked to Cys 186 and Cys 176 is linked to Cys 182, as required by the present claims, Alkerlind-Stopner does not anticipate the claimed invention.

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b).

***Rejection under 35 U.S.C. §103(a)***

Claims 1-15, 19-20, 22, 24, and 26 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Langedijk (U.S. Pat. No. 6,077,511) and Alkerlind-Stopner (*J. Virology* 64: 5143-5148 (1990)), in further view of Guichard (*PNAS* 91: 9765-9769 (1994)). Applicant respectfully traverses this rejection.

As discussed above, neither Langedijk nor Alkerlind-Stopner discloses the disulfide bonding pattern required by the claims of the present invention. Guichard merely discloses retro-inverso-peptidomimetic analogues of natural L-peptides. This reference in combination with Langedijk or Alkerlind-Stopner would not allow one to arrive at the present invention, because none of these references teaches or suggests the claim element wherein Cys 173 is linked to Cys 186 and Cys 176 is linked to Cys 182. The disulfide bonding pattern within the highly conserved, cysteine rich portion of the ectodomain of the RSV G protein was determined empirically by Applicant. This bonding pattern, disclosed in the specification and required by the claims, would not be obvious to one of skill in the art.

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

## CONCLUSION

Applicant has, by way of the amendments and remarks presented herein, removed the issues for the rejections and addressed all issues that were raised in the outstanding Office Action. Accordingly, reconsideration and allowance of the pending claims are respectfully requested. If it is determined that a telephone conversation would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 415852000100. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: December 20, 2001

By: Jill A. Jacobson  
Jill A. Jacobson  
Reg. No. 40,030

Morrison & Foerster LLP  
755 Page Mill Road  
Palo Alto, California 94304-1018  
Telephone: (650) 813-5876  
Facsimile: (650) 494-0792

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**In the Claims:**

1. (Thrice Amended)            A compound [having structural homology to] consisting essentially of a contiguous sequence of amino acids within the sequence representing residues 149-197 of the G protein of respiratory syncytial virus, [in which] wherein

- a)     no oligosaccharide is linked to potential serine, threonine or asparagine attachment sites;
- b)     four cysteine residues are involved in disulphide linkages; and
- c)     the pattern of disulphide linkage is Cys 173 linked to Cys 186, and Cys 176 linked to Cys 182,

[and] or a structural homologue thereof, in which said compound possesses a biological activity of respiratory syncytial virus G protein.

2. (Once Amended)            A compound according to claim 1, [in which] wherein the respiratory syncytial virus is selected from the group consisting of human RSV subtype A, human RSV subtype B, bovine RSV, and mutants and variants thereof.

3. (Twice Amended)            A compound according to [Claim] claim 1, [in which] wherein the compound is a peptide corresponding to amino acids 158 to 196 of the RSV G protein.

4. (Twice Amended) A compound according to [Claim] claim 1, [in which] wherein the compound is a peptide [corresponds] corresponding to amino acids 165 to 187 of the RSV G protein.

6. (Once Amended) A compound [having structural homology to] consisting essentially of a contiguous sequence of amino acids within the sequence representing residues 149-197 of the G protein of RSV, or a structural homologue thereof, wherein [in which] at least one of cysteines 173, 176, 182 and 186 is absent or blocked, and in which said compound is not glycosylated, and has the ability to inhibit infectivity of RSV.

7. (Thrice Amended) A compound according to [Claim] claim 6, selected from the group consisting of :

acetyl-KQRQNKPPSKPNNDFHFEVFNFVPCSI $\overline{\text{C}}$ SNNPTCWAIC $\overline{\text{C}}$ KRIPNKKPGKKAmide

acetyl-KQRQNKPPSKPNNDFHFEVFNFVPCSI[C] $\overline{\text{C}}$ GAmide,

in which the cysteine residues are derivatized with acetamidomethyl

fluoresceinisothiocarbamy1 $\beta$ -

alany1KQRQNKPPSKPNNDFHFEVFNFVPCSI $\overline{\text{C}}$ SNNPTCWAIC $\overline{\text{C}}$ KRIPNKKPGKKAmide

fluoresceinisothiocarbamy1 $\beta$ -alany1FHFEVFNFVPCSI $\overline{\text{C}}$ SNNPTCWAIC

KRIPNKKPGKKAmide

benzoylbenzyl-KQRQNKPPSKPNNDFHFEVFNFVPCSI $\overline{\text{C}}$ SNNPTCWAIC $\overline{\text{C}}$ KRIPNKKPGKK

Amide



biotinyl-KQRQNKPPSKPNNDHFHFEVFNFPVCSICSNNPTCWAICKRIPNKKPGKKAmide  
acetyl-FHFEVFNFPVCSICSNNPTCWAICKRIPNKKPGKKAmide.

8. (Once Amended) A compound according to [any one of Claims 1 to 6] claim 1,  
wherein the compound [which] is a peptidomimetic compound.
9. (Twice Amended) A compound according to [any one of Claims 1 to 7] claim 1,  
wherein [in which] one or more amino acids is replaced by its corresponding D-amino acid.
10. (Twice Amended) A compound according to [any one of claims 1 to 7] claim 1,  
wherein [in which] one or more individual amino acids is replaced by an analogous structure.
11. (Twice Amended) A compound [selected from the group consisting of the compounds  
of Claims 1 to 7,] according to claim 1, wherein the compound is labelled with a detectable  
marker.
12. (Twice Amended) A compound according to [Claim] claim 11, [in which] wherein  
the detectable marker is a radioactive label.
13. (Twice Amended) A compound according to claim 11, [in which] wherein the  
detectable marker is a fluorescent, chemiluminescent or enzymic marker.

22. (Thrice Amended) A method of prevention or treatment of *Pneumovirus* infection, comprising the step of administering an effective amount of a compound selected from the group consisting of [the compounds of claims 1 to 7, the compounds of claims 1 to 6 that are peptidomimetic compounds, the compounds of claims 1 to 7 in which one or more amino acids is replaced by its corresponding D-amino acid, and the compounds of claims 1 to 7 in which] a peptide, a peptidomimetic compound, a compound wherein one or more amino acids is replaced by its corresponding D-amino acid, and a compound wherein one or more individual amino acids is replaced by an analogous structure, to a mammal in need of such treatment.

24. (Thrice Amended) A method of immunisation against *Pneumovirus* infection, comprising the step of immunising a mammal at risk of such infection with an immunising-effective dose of a compound selected from the group consisting of [the compounds of claims 1 to 7, the compounds of claims 1 to 6 that are peptidomimetic compounds, the compounds of claims 1 to 7 in which one or more amino acids is replaced by its corresponding D-amino acid, and the compounds of claims 1 to 7 in which] a peptide, a peptidomimetic compound, a compound wherein one or more amino acids is replaced by its corresponding D-amino acid, and a compound wherein one or more individual amino acids is replaced by an analogous structure, said compound being immunogenic and having the ability to elicit protective antibody.

26. (Twice Amended) A method according to Claim 24, [in which] wherein the [cell] mammal is susceptible to infection by respiratory syncytial virus.

## PARAMYXOVIRUSES

ATCC Catalogue of Animal Viruses  
+ Antisera, Cultures & Rickettsiae  
6th Ed 1990

**Respiratory syncytial ATCC VR-1302**

Strain: A-2. Reference: Lewis, F.A. *et al.*, *Med. J. Aust.* 2: 932-933, 1961. Preparation: Infected HEP-2 TC. Host of Choice: HEP-2. Incubation: 3-10 days at 32-37°C. Effect: Syncytia formation. Host Range: Mk, PrCK, PrBEK, MRC-5, Vero, HEP-2, HeLa. Deposited and Prepared by: L. Potash. Shipped: Frozen.

**Respiratory syncytial ATCC VR-26**

Strain: Long. Original Source: 17-month-old male with pneumonia, Maryland, 1956. Reference: Chanock, R.M. *et al.*, *Am. J. Hyg.* 66: 281-290, 1957. Preparation: Infected TC supernate. Host of Choice: HEP-2 or KB cells. Incubation: 5-12 days. Effect: CPE (giant cells, syncytia). Host Range: KB, Chang L, HEP-2, HeLa, HAM, MCK cells; infant ferrets (i.n.). Special Characteristics: Non-pathogenic for mouse or guinea pig. Essentially identical strain (CCA) isolated by Morris, J.A. *et al.*, *Proc. Soc. Exp. Biol. Med.* 92: 544-549, 1956. Deposited by: R.M. Chanock. Prepared by: ATCC. Available: Frozen and freeze-dried.

**Respiratory syncytial ATCC VR-955**

Strain: 9320. Original Source: Throat swab from 23-month-old girl with diffuse interstitial pneumonia, Massachusetts, 1977. Reference: Hierholzer, J. and M.J. Hirsch, *J. Infect. Dis.* 140(5): 826-828, 1979. Preparation: Infected TC supernate. Host of Choice: HEP-2 TC. Incubation: 3 days, 37°C. Effect: CPE. Host Range: HEP-2, human embryonic lung fibroblast cells. Special Characteristics: HA not demonstrated. Deposited by: M. Hirsch and E. Keller. Prepared by: ATCC. Shipped: Frozen.

**SA-10 (Simian paramyxovirus) ATCC VR-933**

Strain: Samango. Original Source: Throat swab from an asymptomatic monkey (*Cercopithecus mitis*), South Africa. Reference: Malherbe, H., *South Afr. Med. J.* 37: 407, 1963. Preparation: Infected TC supernate. Host of Choice: Vero kidney cells. Incubation: 5-6 days at 37°C. Effect: CPE. Host Range: VK, BSC-1, BabK TC. Special Characteristics: Hemagglutinates human O, guinea pig and bovine RBC. Deposited and Prepared by: R. Heberling. Shipped: Frozen.

**Subacute sclerosing panencephalitis (SSPE) ATCC VR-804**

Strain: Halle. Original Source: Lymph node biopsies from 12-year-old female with clinical symptoms of dementia, myoclonic seizures and coma. References: Barbosa, L.H. *et al.*, *Science (Washington, DC)* 173: 840, 1971; Hamilton, R. *et al.*, *J. Virol.* 12: 632, 1973. Preparation: Infected TC supernate. Host of Choice: Vero cells. Incubation: 1-3 days. Effect: Extensive syncytia type CPE. Host Range: Vero cells, HeLa and Pr AGMK TC. Special Characteristics: HA produced in rhesus monkey RBC. Deposited by: D.A. Fuccillo. Prepared by: ATCC. Shipped: Freeze-dried.

**Subacute sclerosing panencephalitis (SSPE) ATCC VR-803**

Strain: McClellan. Original Source: Lymph node biopsies from 32-year-old male with visual loss, abnormal behavior, delusions, hallucinations, myoclonic seizures, dementia, dysphagia, severe rigidity and death; Tennessee, 1971. Reference: Cape, C.A. *et al.*, *Arch. Neurol.* 28: 124, 1973. Preparation: Infected TC supernate. Host of Choice: Vero cells. Incubation: 7 days. Effect: Syncytia type CPE. Host Range: Vero cells and HeLa. Special Characteristics: HA produced in rhesus monkey RBC. The HA activity of this virus is specifically blocked by measles antisera. Deposited by: D.A. Fuccillo. Prepared by: ATCC. Available: Frozen and freeze-dried.

**SV-5 ATCC VR-288**

Strain: 21005-2WR. Original Source: Rhesus monkey kidney cell culture, 1954. Reference: Hull, R.N. *et al.*, *Am. J. Hyg.* 63: 204, 1956. Preparation: Infected TC supernate. Host of Choice: LLC-MK2 cells. Incubation: 7 days. Effect: CPE; culture fluid agglutinates GP and C RBC. Host Range: MCK, LLC-MK1, LLC-MK2, LLC-MK3, Pr RhMK cells. Special Characteristics: Strain has many attributes in common with parainfluenza strains, but is antigenically distinct from parainfluenza types 1 and 3. Some antisera for parainfluenza type 2 virus may partially neutralize SV-5. It is partially neutralized by SV-5A antiserum. Contains a CF antigen in common with mumps virus. Frequently higher virus titers are detected by hemadsorption than by CPE. Simian Virus Group V (Hull). Deposited by: R.N. Hull. Prepared by: ATCC. Shipped: Frozen.

**SV-5 (Egg-adapted) ATCC VR-289B**

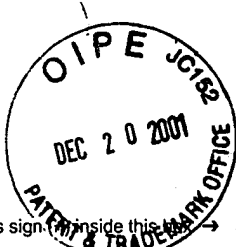
Strain: 5B. Original Source: Rhesus monkey kidney cell culture, 1954. Reference: Hull, R.N. *et al.*, *Am. J. Hyg.* 63: 204, 1956. Preparation: AI fluid. Host of Choice: CE (9-10 days, i.am.). Incubation: *In ovo*, 4 days at 36°C, then overnight at 4°C. Effect: AI fluid agglutinates GP and C RBC. Host Range: CE, LLC-MK2, LLC-MK3 cells. Special Characteristics: Frequently higher virus titers are detected by hemadsorption than by CPE. Deposited by: A. Chappell. Prepared by: ATCC. Shipped: Frozen.

**SV-41 (Simian paramyxovirus 2) ATCC VR-934**

Strain: 514-518. Original Source: Uninoculated TC, cynomolgus monkey (*Macaca fascicularis*). Reference: Miller, R.H. *et al.*, *Am. J. Hyg.* 80: 365-376, 1964. Preparation: Infected TC supernate. Host of Choice: AGMK. Incubation: 4-5 days at 37°C. Effect: CPE. Host Range: Cynomolgus MCK, MCK, AGMK, LLC-MK2, BabK, Vero, HEK. Deposited by: R. Heberling. Prepared by: ATCC. Shipped: Frozen.

**Yucaipa (Avian Paramyxovirus 2) ATCC VR-527**

Strain: Chick/Calif/59 (Bankowski). Original Source: Field case in 3- to 4-week-old chickens with respiratory infection, 1956. Reference: Bankowski, C., *Avian Dis.* 5: 253, 1961. Preparation: AI-Am fluid. Host of Choice: CE. Incubation: 3-8 days. Effect: Mortality or HA activity of AI fluid; respiratory disease in chickens. Host Range: HeLa, PK cells, C fibroblasts. Special Characteristics: Non-lethal for chickens, causes mild transient respiratory distress 6-9 days following intratracheal inoculation. Innocuous for mice. Detection in chickens more easily obtained using HI tests for specific antibodies. Ether inactivates infectivity but not hemagglutinins. Deposited and Prepared by: R.A. Bankowski. Shipped: Frozen.



12.28.01

RECEIVED

JAN 02 2001

TECH CENTER 1600/2000

Please type a plus sign (+) inside this box



Approved for use through 10/31/02. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

# TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number Of Pages In This Submission

31

Application Number

09/202,035

Filing Date

December 17, 1998

First Named Inventor

Jeffrey John GORMAN

Group Art Unit

1648

Examiner Name

B. LI

Attorney Docket No.

415852000100

## ENCLOSURES (check all that apply)

☒ Fee Transmittal Form (original +1 for fee processing) (2 pages total)

☐ Fee Attached

☒ Amendment / Reply (24 pages)

☐ After Final

☐ Affidavits/declarations

☒ Extension of Time Request (1 page)

☐ Express Abandonment Request

☐ Information Disclosure Statement

☐ Certified Copy of Priority Document(s)

☐ Response to Missing Parts/  
Incomplete Application

☐ Response to Missing Parts  
under 37 CFR 1.52 or 1.53

☐ Assignment Papers  
(for an Application)

☐ Drawing(s)

☐ Licensing-related Papers

☐ Petition

☐ Petition to Convert to a  
Provisional Application

☐ Power of Attorney, Revocation  
Change of Correspondence Address

☐ Terminal Disclaimer

☐ Request for Refund

☐ CD, Number of CD(s) \_\_\_\_\_

☐ After Allowance Communication to  
Group

☐ Appeal Communication to Board of  
Appeals and Interferences

☐ Appeal Communication to Group  
(Appeal Notice, Brief, Reply Brief)

☐ Proprietary Information

☐ Status Letter

☒ Other Enclosure(s) (please identify  
below):

- Associate Power of Attorney (3 pages)  
- Return Receipt Post Card

Remarks

## SIGNATURE OF APPLICANT, ATTORNEY OR AGENT

Firm  
or  
Individual Name

Morrison & Foerster LLP, 755 Page Mill Road, Palo Alto, CA 94304-1018

Jill A. Jacobson (Reg. No. 40,030)

Signature

*Jill A. Jacobson*

Date

December 20, 2001

## CERTIFICATE OF MAILING BY "EXPRESS MAIL"

Express Mail Label No.: EL779890322US

Date of Deposit: December 20, 2001

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

*Tamara Alcaraz*  
Tamara Alcaraz

Burden Hours Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Box Patent Application, Washington, DC 20231.

pa-653123